REMARKS

INTRODUCTION:

In accordance with the foregoing, claims 1 and 5 have been amended. No new matter is being presented, and approval and entry are respectfully requested.

Claims 1, 5, 10 and 14 are pending and under consideration. Reconsideration is respectfully requested.

REJECTION UNDER 35 U.S.C. §112:

In the Office Action, at pages 2-4, claims 1, 5, 10 and 14 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and because the specification, while being enabling for the case in which the PrpA protein is one having SEQ ID NO:1, does not reasonably provide enablement for the case in which the PrpA protein is "derived from" the Deinococcus radiodurans PrpA protein such that it ends up having an amino acid sequence other than that of SEQ ID NO:1. This rejection is traversed and reconsideration is requested.

The Advisory Action is unclear. On the Summary page, it says that the proposed amendment will be entered. However, on the attached page, it says "The amendment would overcome the 112, first paragraph, rejections with respect both written description and scope of enablement." (emphasis added) Hence, it is unclear whether the amendment has been entered. Thus, a slight revised amendment, revised for clarity, is provided herewith.

Independent claims 1 and 5 are submitted to be in allowable form under 35 U.S.C. §112, first paragraph, to comply with the written description requirement, and the specification is submitted to be enabling for the case of the PrpA protein having an amino acid sequence of SEQ ID NO: 1, which is obtained from Deinococcus radiodurans. Since claims 10 and 14 depend from claims 1 and 5, respectively, claims 10 and 14 are in allowable form under 35 U.S.C. §112, first paragraph, comply with the written description requirement, and the specification is enabling for the case of the PrpA protein having an amino acid sequence of SEQ ID NO: 1, which is obtained from Deinococcus radiodurans for at least the reasons claims 1 and 5 are in allowable form under 35 U.S.C. §112, first paragraph, comply with the written description requirement, and the specification is enabling for the case of the PrpA protein having an amino acid sequence of SEQ ID NO: 1, which is obtained from Deinococcus radiodurans.

REJECTION UNDER 35 U.S.C. §102:

In the Office Action, at pages 4-5, claims 5 and 14 were rejected under

35 U.S.C. §102(e) in view of Narumi et al. (US 2003/0143707; hereafter, Narumi) This rejection is traversed and reconsideration is requested.

Although the Examiner has submitted, in the Advisory Action, that the Rule 1.132 Declaration was not considered, it is resubmitted herewith with the argument that a response was filed in the non-final Office Action of June 27, 2006 that was believed to be sufficient. However, in view of the Examiner's response thereto, it was recognized that it was necessary to bring to the Examiner's attention the facts recited in the Rule 1.132 Declaration. It is respecfully submitted that the facts of this matter make it clear that the portions of the Narumi application relied on as prior art and the subject matter of the claims in question represent the work of a common inventive entity. Hence, the Narumi application is not available as an anticipatory reference, and claims 5 and 14 are not anticipated under 35 U.S.C. §102(e) in view of Narumi et al. (US 2003/0143707).

Reconsideration is respectfully requested. The arguments are repeated below for the Examiner's convenience.

It is respectfully submitted that 35 U.S.C. §102(e) states:

> A person shall be entitled to a patent unless -
> ...
> (e) the invention was described in - (1) an application for a patent, published under section 122(b), by another filed in the United states before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or" (emphasis added)

The statute explicitly states that the reference at issue must be "by another." Even though the court has concluded that patents issued to the same inventive entity are not prior art by admission or under section 102(e), that does not end the matter at hand. In the present case, even though the Narumi application and the present application both appear to be assigned to the Japan Atomic Energy Research Institute, the Narumi application and the present application are not invented by the same inventive entity, i.e., the inventors were two groups that do not totally match. To fully answer the question – whether the Narumi application is prior art as to the present application – we must look beyond the superficial fact that these have different inventive entities. What is significant is not merely the differences in the listed inventors, but whether the portions of the Narumi application relied on as prior art and the subject matter of the claims in question, represent the work of a common inventive entity. See In re DeBaun, 687 F.2d 459, 462, 214 USPQ 933, 935 (CCPA 1982).

In DeBaun, the examiner rejected DeBaun's application as being obvious in light of U.S. Patent No. 3,964,278 ("the '278 patent") issued to DeBaun and Noll less than one year before DeBaun's filing date. DeBaun submitted a declaration that he was the sole inventor of everything in the '278 patent that was relied on by the examiner as the basis of the obviousness rejection in the subsequent application. Id. at 461, 214 USPQ at 934-35. In light of the declaration, the court's predecessor reversed the examiner's rejection, holding that the examiner should have considered the "evidentiary" issue of "who invented the subject matter disclosed by [the reference] which was relied on to support the rejection." Id. at 462, 214 USPQ at 935 (citing In re Land, 368 F.2d 866, 879-80 n.11, 151 USPQ 621, 633 n.11 (CCPA 1966)) (alterations in original). While DeBaun was an appeal from the PTO in which the reference was asserted as prior art for purposes of patentability, the same principle applies to the use of a reference in a post-issuance validity challenge. See DeGraffenreid v. United States, 20 Cl. Ct. 458, 467, 16 USPQ2d 1321, 1328 (1990).

Enclosed herein is a Declaration in which Katsuya Satoh and Issay Narumi recite that they are the inventors of the portion of the subject matter disclosed in U.S. Patent Application Publication No. 2003/030143707 A1 which was utilized in the 35 U.S.C. §102(e) Office Action rejection of claims 5 and 14 of the above-cited application mailed February 21, 2007. Hence, it is respectfully submitted that the Narumi application is not available as an anticipatory reference, and claims 5 and 14 are not anticipated under 35 U.S.C. §102(e) in view of Narumi et al. (US 2003/0143707).

REJECTION UNDER 35 U.S.C. §103:

In the Office Action, at pages 5-6, claims 1 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Namuri et al. in view of Chaubron et al. (US 6,309,838; hereafter, Chaubron The reasons for the rejection are set forth in the Office Action and therefore not repeated. The rejection is traversed and reconsideration is requested.

It is respectfully submitted that 35 U.S.C. §103(a), 35 U.S.C. §103(c)(1) states:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. (emphasis added)

A "same person" includes a "same company."

Hence, §103(c)(1) provides a safe harbor, and Narumi may not be cited as an obviousness reference under 35 U.S.C. §103(a). Since Chaubron does not teach or suggest a method for detecting *in situ* a DNA strand break, comprising: binding a PrpA protein having an

amino acid sequence of SEQ ID NO: 1, which is obtained from Deinococcus radiodurans, to a DNA strand break; and detecting *in situ* the PprA protein bound to the DNA strand break using an antibody or a fragment thereof which specifically binds to the PprA protein (suggested amended claim 1), amended claim 1, and claim 10 which depends therefrom, are patentable under 35 U.S.C. §103(a) over Narumi and Chaubron.

As previously noted, it is respectfully submitted that, the problem to be solved by the invention of Chaubron is to provide a method for detecting a DNA strand break which is located on the purified DNA which is mutated by mutagens or on the DNA which is extracted from cells treated with mutagens. In order to solve the problem, Chaubron uses "a cell extract which is purified to a greater or lesser degree with respect to the presence of a ligand which is endogenous and of DNA which is endogenous to said recognition medium" to recognize the DNA damage (see, column 10, lines 8-11 and Examples 1-5). However, the damaged DNA within each cell cannot be recognized by a cell extract in situ due to the presence of the endogenous proteins included in the cell extract which have an inhibitory effect on the binding of "the ligand" to the damaged DNA. Therefore, the method of Chaubron can only be applicable to a purified DNA or a DNA extracted from a cell.

In contrast, the present invention is directed to a method for directly measuring the in vivo distribution of DNA strand break in the cell or of the frequency of generation of DNA strand break(s) within the intracellular organelles (such as mitochondria) in situ. That is to say, in the present invention, DNA strand breaks can be detected within each cell (in situ) without extracting the cellular DNA.

The method of the present invention is characterized by the use of a purified PprA protein having Deinococcus radiodurans rather than a cell extract prepared from various types of cells. Since a purified PprA protein having Deinococcus radiodurans does not include any endogenous proteins which inhibit the binding of the PprA protein to the damaged DNA, the DNA strand breaks are effectively detected within mammalian cells in situ without the detection being inhibited by the endogenous protein included in the cell extract.

Further, the present invention demonstrates an unexpected advantageous effect over the prior art in that the present invention distinguishes the DNA strand break generated in the nucleus of each cells from the DNA strand break generated in the mitochondria, since the present invention can directly measure the in vivo distribution of DNA strand break within the cell or of the frequency of generation of DNA strand breaks) within the intracellular organelles (such as mitochondria) in situ.

Since the present invention exerts an advantageous effect over the invention of Chaubron, as described above, it is respectfully submitted that amended independent claim 1 is unobvious for those ordinarily skilled in the art to use the PprA protein in any detection method taught by Chaubron, and therefore is patentable under 35 U.S.C. §103(a) over Namuri et al. (JP 2003-052376) in view of Chaubron et al. (USPN 6,309,838) since Narumi may not be cited as an obviousness reference under 35 U.S.C. §103(a). Since claim 10 depends from amended independent claim 1, claim 10 is patentable under 35 U.S.C. §103(a) over Namuri et al. (JP 2003-052376) in view of Chaubron et al. (USPN 6,309,838) for at least the reasons amended independent claim 1 is patentable under 35 U.S.C. §103(a) over Namuri et al. (JP 2003-052376) in view of Chaubron et al. (USPN 6,309,838).

CONCLUSION:

In accordance with the foregoing, it is respectfully submitted that all outstanding objections and rejections have been overcome and/or rendered moot. And further, that all pending claims patentably distinguish over the prior art. Thus, there being no further outstanding objections or rejections, the application is submitted as being in condition for allowance which action is earnestly solicited.

If the Examiner has any remaining issues to be addressed, it is believed that prosecution can be expedited by the Examiner contacting the undersigned attorney for a telephone interview to discuss resolution of such issues.

If there are any underpayments or overpayments of fees associated with the filing of this Amendment, please charge and/or credit the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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